for continued approval of a CLIA exemption. CMS provides notice of the materials that must be submitted as part of the reapplication procedure.

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or validation review, must furnish CMS, upon request, with the reapplication materials CMS requests. CMS establishes a deadline by which the materials must be submitted.

(d) *Notice.* (1) CMS provides written notice, as appropriate, to the following:

(i) An accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and CMS is initiating a review of the accreditation organization's deeming authority.

(ii) A State licensure program indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State's laboratories.

(2) The notice contains the following information:

(i) A statement of the discrepancies that were found as well as other related documentation.

(ii) An explanation of CMS's review process on which the final determination is based and a description of the possible actions, as specified in § 493.575, that CMS may impose based on the findings from the comparability or validation review.

(iii) A description of the procedures available if the accreditation organization or State licensure program, as applicable, desires an opportunity to explain or justify the findings made during the comparability or validation review.

(iv) The reapplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.

§ 493.575 Removal of deeming authority or CLIA exemption and final determination review.

(a) *CMS review.* CMS conducts a review of the following:

(1) A deeming authority review of an accreditation organization's program if the comparability or validation review produces findings, as described at § 493.573. CMS reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(a) to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) An exemption review of a State's licensure program if the comparability or validation review produces findings, as described at § 493.573. CMS reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(b) to reevaluate whether the licensure program continues to meet all these criteria.

(3) A review of an accreditation organization or State licensure program, at CMS's discretion, if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's accreditation or State's licensure process that provide evidence that the requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(4) A review of the accreditation organization or State licensure program whenever validation inspection results indicate a rate of disparity of 20 percent or more between the findings of the organization or State and those of CMS or a CMS agent for the following periods:

(i) One year for accreditation organizations.

(ii) Two years for State licensure programs.

(b) *CMS action after review.* Following the review, CMS may take the following action:

(1) If CMS determines that the accreditation organization or State has failed to adopt requirements equal to, or more stringent than, CLIA requirements, CMS may give a conditional approval for a probationary period of its deeming authority to an organization 30 days following the date of CMS's determination, or exempt status to a State within 30 days of CMS's determination, both not to exceed 1 year, to

afford the organization or State an opportunity to adopt equal or more stringent requirements.

(2) If CMS determines that there are widespread or systematic problems in the organization's or State's inspection process, CMS may give conditional approval during a probationary period, not to exceed 1 year, effective 30 days following the date of the determination.

(c) *Final determination.* CMS makes a final determination as to whether the organization or State continues to meet the criteria described in this subpart and issues a notice that includes the reasons for the determination to the organization or State within 60 days after the end of any probationary period. This determination is based on an evaluation of any of the following:

(1) The most recent validation inspection and review findings. To continue to be approved, the organization or State must meet the criteria of this subpart.

(2) Facility-specific data, as well as other related information.

(3) The organization's or State's inspection procedures, surveyors' qualifications, ongoing education, training, and composition of inspection teams.

(4) The organization's accreditation requirements, or the State's licensure or approval requirements.

(d) *Date of withdrawal of approval.* CMS may withdraw its approval of the accreditation organization or State licensure program, effective 30 days from the date of written notice to the organization or State of this proposed action, if improvements acceptable to CMS have not been made during the probationary period.

(e) *Continuation of validation inspections.* The existence of any validation review, probationary status, or any other action, such as a deeming authority review, by CMS does not affect or limit the conduct of any validation inspection.

(f) *Federal Register notice.* CMS publishes a notice in the FEDERAL REGISTER containing a justification for removing the deeming authority from an accreditation organization, or the CLIA-exempt status of a State licensure program.

(g) *Withdrawal of approval-effect on laboratory status*—(1) *Accredited laboratory.* After CMS withdraws approval of an accreditation organization's deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.

(2) *CLIA-exempt laboratory.* After CMS withdraws approval of a State licensure program, the exempt status of each licensed or approved laboratory in the State continues in effect for 60 days after a laboratory receives notification from the State of the withdrawal of CMS's approval of the program.

(3) *Extension.* After CMS withdraws approval of an accreditation organization or State licensure program, CMS may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application for the appropriate certificate to CMS or a CMS agent before the initial 60-day period ends.

(h) *Immediate jeopardy to patients.* (1) If at any time CMS determines that the continued approval of deeming authority of any accreditation organization poses immediate jeopardy to the patients of the laboratories accredited by the organization, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of deeming authority for that accreditation organization.

(2) If at any time CMS determines that the continued approval of a State licensure program poses immediate jeopardy to the patients of the laboratories in that State, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of that State licensure program.

(i) *Failure to pay fees.* CMS withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§493.645(a) and 493.646(b).

(j) *State refusal to take enforcement action.* (1) CMS may withdraw approval of a State licensure program if the State

refuses to take enforcement action against a laboratory in that State when CMS determines it to be necessary.

(2) A laboratory that is in a State in which CMS has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA requirements.

(k) *Request for reconsideration.* Any accreditation organization or State that is dissatisfied with a determination to withdraw approval of its deeming authority or remove approval of its State licensure program, as applicable, may request that CMS reconsider the determination, in accordance with subpart D of part 488.

Subpart F—General Administration

SOURCE: 57 FR 7138, 7213, Feb. 28, 1992, unless otherwise noted.

§ 493.602 Scope of subpart.

This subpart sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of accredited laboratories and of CLIA-exempt laboratories.

[60 FR 20047, Apr. 24, 1995]

§ 493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in § 493.3.

[58 FR 5212, Jan. 19, 1993]

§ 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance, as applicable. Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates and certificates of compliance, the costs include issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, evaluating which procedures, tests or examinations meet the criteria for inclusion in the appropriate complexity category, and implementing section 353 of the PHS Act.

(2) For a certificate of waiver, the costs include issuing the certificate, collecting the fees, determining if a certificate of waiver should be issued, evaluating which tests qualify for inclusion in the waived category, and other direct administrative costs.

(3) For a certificate for PPM procedures, the costs include issuing the certificate, collecting the fees, determining if a certificate for PPM procedures should be issued, evaluating which procedures meet the criteria for inclusion in the subcategory of PPM procedures, and other direct administrative costs.

(4) For a certificate of accreditation, the costs include issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and other direct administrative costs.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on the category of test complexity, or on the category of test complexity and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, and proficiency testing purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in § 493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in § 493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate for PPM procedures, certificate of waiver, certificate of accreditation, or certificate of compliance is the amount in effect at the time the application is received.